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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,677	10/24/2000	Naohiko Katagiri	KATAGIRI 3	3721
7590 03/10/2004				
BROWDY AND NEIMARK, P.L.L.C.		EXAMINER		
624 Ninth Street, N.W.		NOLAN, SANDRA M		
Washington, DC 20001-5303		ART UNIT PAPER NUMBER		

1772

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/694,677

Applicant(s)

KATAGIRI ET AL.

Examiner

Sandra M. Nolan

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09 Jan 2001.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claims***

1. Claims 1-21 are pending.

### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Abstract***

3. The abstract, which appears on the 47<sup>th</sup> page of the "Miscellaneous Incoming Letter" [i.e., the patent application] dated 24 October 2000 in the office's eDAN/IFW database is acceptable.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 09 January 2001 was considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 11103781A (abstract).

The '781 abstract teaches dough whose surface is coated with trehalose and then baked (novelty section) to yield shaped rice crackers (advantage section).

The property set out in claim 3 would be inherent in the '781 abstract product because it uses the same material recited in claim 1.

7. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 11299422A (abstract).

The '422 abstract teaches that molded articles are made from compositions containing trehalose (first sentence of abstract).

The property set out in claim 3 would be inherent in the '422 abstract product because it uses the same material recited in claim 1.

8. Claims 1-10 and 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Briellatt et al (US 5,510,115).

Briellatt teaches water soluble compositions (abstract) used to make solid "formed" articles that are used to deliver agents into medical fluids in controlled ways (col. 3, lines 64-67). The compositions contain trehalose as a sugar (col. 5, line 49), which may be one of a mixture of sugars (col. 5, lines 45-46). The sugar used may be amorphous (col. 5, line 56). Glycerol, a polyol, may be used at a concentration of 1% (col. 6, line 9). The compositions contain less than 1% water (col. 5, lines 61-63).

The articles made may be 35mm x 32mm x 2.5mm in size (col. 7, about line 33).

The examiner interprets "formed" to mean shaped.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 6,187,330) in view of Breillatt.

Wang teaches devices for the controlled release of drugs (abstract). The devices contain trehalose (col. 3, line 50), a surfactant (col. 4, line 31) and a polyol (col. 4, line 39). The devices are made by lyophilizing an aqueous solution containing trehalose (as a thermoprotectant) and drug to yield a cake that is later powdered (col. 4, lines 42-48). The resultant lyophile powder is mixed with a polymer and shaped (col. 5, lines 16-45). Trehalose can be present at a 4% concentration (col. 4, Table 1).

The examiner considers a drug to be a pharmaceutical and the making of the cake to be pressure forming.

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Wang fails to teach that the trehalose-containing solid contains less than 2.4 wt% water.

Breillatt is discussed above.

The patents are analogous because they both deal with medicinal delivery systems.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the low moisture contents of Breillatt when making the cakes of Wang in order to insure that the resultant device of Wang can be introduced into medical fluids in controlled way.

The motivation to employ the low moisture contents of Breillatt when making the cakes of Wang is found in Briellatt, where it teaches that its water soluble compositions (abstract) are used to make solid "formed" articles that are used to deliver agents into medical fluids in controlled ways (col. 3, lines 64-67).

It is deemed desirable to make medical devices that can introduce drugs into fluids in controlled ways in order to better manage the pharmaceutical effects of the drugs being administered.

### ***Conclusion***

Any inquiry concerning this communication should be directed to Sandra M. Nolan, whose telephone number is 571/272-1495. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

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If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 571/272-1498. The USPTO fax number is 703/872-9306.



S. M. Nolan  
Patent Examiner  
Technology Center 1700

SMN/smn  
09694677(20040303)